



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

Buranta 8/6/18

## DOCUMENT CONTAINS CBI

DP BARCODE No.: 445256; FILE/ REG No.: 19713-641; ACTION CODE: R351;

PRODUCT NAME: 2, 4-D TECHNICAL; DECISION No.: 536772; PC Code(s): 030001;

**DATE:** August 6, 2018

SUBJECT: Product Chemistry Review of 2, 4-Dichlorophenoxyacetic Acid Technical (2.4-D)

Alternate CSF #7

FROM: Akiva Ahramovitch, Ph.D.

CITAB/RD (7505P)

THROUGH: Shyam B. Mathur, Ph.D.

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CITAB /RD (7505P)

TO: Grant Rowland/Kathryn Montague, PM 23

Herbicide Branch / Registration Division (7505P)

**COMPANY NAME: Drexel Corporation** 

**FORMULATION: Technical** 

### INTRODUCTION:

The registrant has submitted an application for a new manufacturing site at for a registered 2, 4- Dichlorophenoxyacetic Acid Technical Herbicide. The registrant provided group A product chemistry data including five batches analysis encompassing the analysis of poly chlorinated dibenzofurans and dibenzodioxins in MRID 504400-01. The registrant has a manufacturing sites in

The registrant has submitted alternate CSF#7 for the alternate manufacturing site in dated October 27, 2017 listing 2, 4-D at 98.32%. The label claim is 98.61% 2, 4-D.

CITAB has been asked to determine the acceptability of product chemistry data submitted to support the new manufacturing site by

#### SUMMARY OF FINDINGS:

- 1) The five batch analyses for the proposed manufacturing site by ranged from 98.37 to 98.75% for the active ingredient 2, 4-D for an average of 98.61%. The basic CSF lists the active ingredient at 98.2%. The label claim is for 98.2% 2, 4-Dichloroacetic Acid (2, 4-D).
- The manufacturing process is identical to that used in other manufacturing sites to the one listed on alternate CSF #7.
- 3) All the impurities on the basic and alternate CSFs are identical. Levels of toxic impurities are within acceptable level. Levels of toxic impurities are within the upper certified levels shown on the basic CSF.

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4) Analysis for poly-chlorinated dibenzofurans and dibenzo-p-dioxins were conducted in reference to analysis of spiked samples. These impurities of major toxicological significance were not detected in the analysis and were listed on the alternate CSF for the manufacturing site was the detection limit for the certified upper limits. (See Confidential Appendix for Details).

## CONCLUSIONS:

The CITAB has reviewed the product chemistry data submitted for the proposed alternate manufacturing site and has concluded that:

1. Impurities of toxicological significance were analyzed at levels of below 0.1 ppb. Levels of total chlorinated Dioxins were below the levels of detection. The levels of detection are in compliance with the June 15, 1987 Data Call-In Notice for Analytical Chemistry Data on Polyhalogenated Dibenzo-p-Dioxins/Dibenzofurans. No new impurities or unexpected impurities were found.

 The proposed CSF for the alternate CSF#7 dated October 27, 2017 for the manufacturing site by is acceptable.

\*Product ingredient source information may be entitled to confidential treatment\*